APPEAL BRIEF UNDER 37 C.F.R. § 41.37

TABLE OF CONTENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	John D. Hatlestad et al.	Examiner: Sheetal Rangrej	
Serial No.:	10/787,045	Group Art Unit: 3686	
Filed:	February 25, 2004	Docket No.: 279.B27US1	
Customer No.:	45458	Confirmation No.: 4409	
Title:	ADVANCED PATIENT AND MEDICATION THERAPY MANAGEMENT SYSTEM AND METHOD		

APPEAL BRIEF UNDER 37 CFR § 41.37

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The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on July 7, 2010, from the Final Rejection of claims 1-11, 13-14, and 16-28 of the above-identified application, as set forth in the Office Action mailed on April 7, 2010.

Pursuant to MPEP § 1204.01, it is believed that the Appeal Brief fees previously paid by Appellant with the Appeal Brief filed August 31, 2009 will be applied to this Appeal Brief reinstatement. However, if the Commissioner determines that additional fees are required, please charge the Appeal Brief fee, as well as any additional required fees, to Deposit Account No. 19-0743. The Appellant respectfully requests consideration and reversal of the Examiner's rejections of the pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Cardiac Pacemakers, Inc., as evidenced by the Assignment recorded on February 29, 2004, on Reel 015028, Frames 0892-0895. Cardiac Pacemakers, Inc. is a subsidiary of Boston Scientific Corp.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

In accordance with 37 CFR 41.37(c)(1)(iii) requiring a statement of the status of all claims, pending and canceled, Appellant submits the following:

The present application was filed on February 25, 2004 with claims 1-28. A Non-Final Office Action was mailed October 9, 2007. In the response filed March 10, 2008, claim 15 was canceled. A Final Office Action was mailed June 11, 2008. In response, claim 12 was canceled in the Amendment and Response filed with the Request for Continued Examination on September 11, 2008. A Non-Final Office Action was mailed September 30, 2008. A Final Office Action was mailed April 1, 2009. A decision on a Pre-Appeal Brief was mailed July 20, 2009. An Appeal Brief was filed on August 31, 2009. A Non-Final Office Action was mailed on December 11, 2009. A Final Office Action was mailed on April 7, 2010. An Advisory Action was mailed on June 23, 2010. Claims 1-11, 13, 14, and 16-28 stand twice rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

In response to the Final Office Action mailed April 7, 2010, Appellant filed an Amendment and Response on June 7, 2010. As indicated in the Advisory Action mailed June 23, 2010, the amendments after the Final Office Action were entered for the purposes of this Appeal.

5. SUMMARY OF CLAIMED SUBJECT MATTER

This summary is presented in compliance with the requirements of Title 37 C.F.R. § 41.37(c)(1)(v), mandating a "concise explanation of the subject matter defined in each of the independent claims involved in the appeal …". Nothing contained in this summary is intended to change the specific language of the claims described, nor is the language of this summary to be construed so as to limit the scope of the claims in any way.

Aspects of the present inventive subject matter include, but are not limited to, advanced patient and medication therapy management systems and methods.

INDEPENDENT CLAIM 1 (see, e.g., FIGS. 1, 3, and 4; page 5, line 27 through page 16, line 11)

1. A medication storage, therapy and consumption management system (100), comprising:

an implantable device (102, 104, 105, or 106) configured to implantably electrically monitor fluid retention;

an external, non-ambulatory pill-dispensing containment unit (260) configured to accessibly house diuretic medication, the containment unit including a diuretic medication pill receptacle (264) configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication; and

a health management host system (112) coupled to the containment unit in a manner that allows data transmission;

said containment unit including a communications and control system (211) that records and transmits data relating to a medication event, the medication event data including information related to the dispensing, said containment unit control system further providing for transmitting and receiving medication therapy data;

said health management host system configured to receive data related to the medication event, receive patient physiological data including fluid retention data collected by the implantable device, analyze the patient physiological data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data.

INDEPENDENT CLAIM 9 (see, e.g., FIGS. 1, 3, and 4; page 5, line 27 through page 16, line 11)

9. An electronic patient health management system (100), comprising:

an implantable medical measurement device (102, 104, 105, or 106) for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data;

an external, non-ambulatory, pill-dispensing medication therapy management device (260) configured to accessibly house diuretic medication, the medication therapy management device including a diuretic medication pill receptacle (264) configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication, the medication therapy management device being configured to store medication event data related to at least one of dispensing or patient consumption of medication, the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement device and the medication event data; and

a patient wellness host system (112), communicatively coupled to the medication therapy management device, configured to receive the processed data and use the processed data to generate a diuretic medication therapy regimen.

INDEPENDENT CLAIM 24 (see, e.g., FIGS. 1 and 3; page 5, line 27 through page 16, line 11)

24. A method for remote management of a medication therapy using an external, non-ambulatory, pill-dispensing medication containment unit (260), the method comprising:

alerting a patient when it is time to carry out a diuretic medication step of a first therapeutic plan;

sensing when the external, non-ambulatory, pill-dispensing medication containment unit is engaged and recording the same as a medication event, the containment unit including a diuretic medication pill receptacle (264) configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication, wherein the medication event data includes information related to the dispensing;

implantably electrically sensing fluid retention data;

receiving patient physiological data including the implantably-sensed fluid retention data;

processing said patient physiological data and said medication event data; and

generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data.

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to each of the appended claims and its legal equivalents for a complete statement of the invention. Page and line numbers and reference symbols from the drawings are exemplary in nature. Further, these page and line numbers are not intended to be an exhaustive listing of each and every location where the particular subject matter can be found in the specification.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Rejection of Claims Under § 102

Claims 1-6, 8-10, 13, 14, 16-22, and 24-27 were clearly erroneously rejected under 35 U.S.C. 102(e) for anticipation by Warkentin et al. (U.S. Patent No. 6,824,512).

The Rejection of Claims Under § 103

Claims 7, 11, 23, and 28 were clearly erroneously rejected under 35 U.S.C. 103(a) over Warkentin et al. in view of Mann et al. (U.S. Patent Application Publication No. 2004/0147969).

7. ARGUMENT

A) The Applicable Law

A.1. Standard of Review

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent."[1]

A.2. The Applicable Law under 35 U.S.C. §102(e)

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.[2] To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.[3] The identical invention must be shown in as complete detail as is contained in the claim.[4] The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e. identity of terminology is not required.[5]

A.3. The Applicable Law under 35 U.S.C. §103(a)

The determination of obviousness requires that the Examiner meet his or her burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness.[6] As discussed by the U.S. Supreme Court in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), the

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[1] *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992)(citations omitted); *see In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).
[2] M.P.E.P § 2131.
[3] *PPG Industries, Inc. V. Guardian Industries Corp.*, 75 F.3d 1558, 37 USPQ2d 1618 (Fed. Cir. 1996).
[4] *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).
[5] *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).
[6] *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence.[7] The legal conclusion, that a claim is obvious within § 103(a), depends on at least four underlying factual issues set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations.

In combining prior art references to construct a *prima facie* case, the Examiner must show some objective evidence in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant portions of the references.[8] However, the level of skill is generally that of the person who follows the conventional wisdom in the art.[9] An invention can be obvious even though the reason to combine prior art teachings is not found in a specific reference.[10] But the requirement of some reason to combine references in a *prima facie* case of obviousness is emphasized in the Federal Circuit opinion, *In re Lee*,[11] which notes that the reason must be supported by some evidence in the record.

The *KSR* Court merely rejected a rigid application of any "teaching, suggestion, motivation" test; it recognized that a more flexible conception of the test is entirely consistent with the *Graham* analysis.[12] The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention.[13] References must be considered in their entirety, including parts that teach away from the claims.[14] The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.[15]

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[7] *See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1336-37, 75 USPQ2d 1051 (Fed. Cir. 2005).
[8] *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).
[9] *Standard Oil Co. v. American Cyanamid Co.,* 774 F.2d 448, 454, 227 USPQ 293, 298 (Fed. Cir. 1985).
[10] *See In re Oetiker*, 977 F.2d 1443, 1448, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992).
[11] *In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).
[12] *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401, 127 S.Ct. 1727, 1731 (2007).
[13] *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).
[14] *See* M.P.E.P. § 2141.02.
[15] *See generally In re Mills*, 916 F.2d 680, 16 USPQ2d 1430, 1432-1433 (Fed. Cir. 1990); M.P.E.P. § 2143.01.

Notably, the *KSR* Court affirmed that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." [16] The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103, recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art.[17] Moreover, when a reference teaches away from a claimed invention, this fact highly probative that the reference would not have rendered the claimed invention obvious to one of ordinary skill in the art.[18] If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.[19] The CCPA has also noted that "[t]he court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is, we must view the prior art without reading into that art appellant's teachings."[20] Thus, these principles have not been changed by the ruling in *KSR*.

B) Discussion of the Rejections

B.1. Claims 1-6, 8-10, 13, 14, 16-22, and 24-27 were clearly erroneously rejected under 35 U.S.C. 102(e) for anticipation by Warkentin et al. (U.S. Patent No. 6,824,512).

Appellant requests reversal of the rejection of claims 1-6, 8-10, 13, 14, 16-22, and 24-27 because of clear error. A proper *prima facie* case of anticipation has not been established.

1. Warkentin et al. fails to establish each and every element recited or incorporated into the claims

Warkentin et al. fails to establish each and every recitation in claims 1-6, 8-10, 13, 14, 16-22, and 24-27. Independent claims 1, 9, and 24 recite or similarly recite "an implantable device configured to implantably electrically monitor fluid retention; an external, non-

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[16] *See In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1335-1336 (CA Fed. 2006) (cited with approval in *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41 (2007)).
[17] *See In re Bond, 910* F.2d 831,834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied,* 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990).
[18] *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 1990 WL 10072072, 15 USPQ2d 1704, 1713 (Tex. 1990).
[19] *See generally In re Ratti*, 270 F.2d 810, 123 USPQ 349, 352 (CCPA 1959).
[20] *In re Sponnoble,* 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969).

ambulatory pill-dispensing containment unit configured to accessibly house diuretic medication, the containment unit including a diuretic medication pill receptacle configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication; . . . said health management host system configured to receive data related to the medication event, receive patient physiological data including fluid retention data collected by the implantable device, analyze the patient physiological data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data."

Warkentin et al. fails to establish an implantable device to electrically monitor fluid retention, a pill-dispensing containment unit configured to accessibly house diuretic medication, and/or generating a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data. Neither the portions of Warkentin et al. cited at pages 2-3 of the Final Office Action, dated April 7, 2010 ("the Office Action"), nor any other portion of Warkentin et al., make any reference to such features, as recited in the independent claims of the present application.

Warkentin et al. merely refers to a system for use in a neural stimulation or cardiac rhythm and therapy context—not in a fluid monitoring and treatment context. For instance, Warkentin et al. states that "IMD 10 contains a microprocessor for timing, sensing and pacing functions consistent with preset programmed functions. Similarly, IMDs 10' and 10" are microprocessor-based to provide timing and sensing functions to execute the clinical functions for which they are employed. For example, IMD 10' could provide neural stimulation to the brain via electrode 30 and IMD 10" may function as a drug delivery system that is controlled by electrode 36." (Warkentin et al. at col. 6, lines 34-41.) Warkentin et al. further states that

> [t]he IMDs contemplated by the present invention include a cardiac pacemaker, a defibrillator, a pacer-defibrillator, implantable monitor (Reveal), cardiac assist device, and similar implantable devices for cardiac rhythm and therapy. Further the IMD units contemplated by the present invention include electrical stimulators such as, but not limited to, a drug delivery system, a neural stimulator, a neural implant, a nerve or muscle stimulator or any other implant designed to provide physiologic assistance or clinical therapy.

(Warkentin et al. at col. 12, lines 13-21.)

The Office Action at page 2 contends that Warkentin et al. describes an implantable device configured to implantably electrically monitor fluid retention, and the Advisory Action, dated June 23, 2010, contends that "the Warkentin reference teaches the measurement of physiologic parameters (i.e. sensing fluid retention data)." However, Warkentin et al. fails to describe or enable implantably electrically monitoring fluid retention. Warkentin et al. merely states that "IMDs 10, 10' and 10" chronically monitor physiologic parameters of the patient," (col. 10, lines 66-67). Then, as noted above, Warkentin et al. merely goes on to describe various cardiac rhythm and therapy devices and electrical stimulators. Warkentin et al. includes no reference to an implantable device configured to electrically monitor fluid retention, a pill-dispensing containment unit configured to accessibly house diuretic medication, and/or generating a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data. The mere vague, tenuous, and remote mention in Warkentin et al. of "chronically monitor[ing] physiologic parameters" simply does not constitute an enabling disclosure of the elements recited or incorporated in claims 1-6, 8-10, 13, 14, 16-22, and 24-27. Accordingly, a proper *prima facie* case of anticipation has not been established.

2. Warkentin et al. fails to show the identical invention in as complete detail or as arranged in the claims

Warkentin et al. fails to establish every feature recited or incorporated in claims 1-6, 8-10, 13, 14, 16-22, and 24-27 in as complete detail or as arranged as in the claims. The cited portions of Warkentin et al. fail to support the Office Action's characterizations of Warkentin et al. The vague and tenuous reference in the cited portion of Warkentin et al. (col. 10, line 66 – col. 11, line 12) to monitoring physiologic parameters fails to include any description related to an implantable device electrically monitoring fluid retention. There is similarly no description in Warkentin et al. related to accessibly housing diuretic medication. Additionally, Warkentin et al. does not describe a "health management host system configured to . . . analyze the patient physiological data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data."

Objectively viewed, Warkentin et al. merely refers to monitoring physiologic parameters and states that "IMDs 10, 10' and 10" could alert the physician or clinician to confer with the

patient." (*See* Warkentin et al. at col. 10, line 66 – col. 11, line 6.) There is no description in Warkentin et al. to use its system for generating a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data. Merely mentioning that the Warkentin et al. implantable medical device could somehow alert the physician or clinician to confer with the patient falls well short of analyzing the data and generating a diuretic medication therapy regimen. As such, Warkentin et al. fails to establish every feature recited or incorporated in claims 1-6, 8-10, 13, 14, 16-22, and 24-27 in as complete detail or as arranged as in the claims. Accordingly, a proper *prima facie* case of anticipation has not been established.

B.2. Discussion of the rejection of claims 7, 11, 23, and 28 under 35 U.S.C. 103(a) as being unpatentable over Warkentin et al. in view of Mann et al. (U.S. Patent Application Publication No. 2004/0147969).

Appellant requests reversal of the rejection of claims 7, 11, 23, and 28 because of clear error in that a proper *prima facie* case of obviousness has not been established. Appellant also respectfully submits that dependent claims 7, 11, 23, and 28 are patentable for at least the reasons stated above for independent claims 1, 9, and 24, from which claims 7, 11, 23, and 28 depend. Accordingly, Appellant respectfully requests reversal of the rejection of claims 7, 11, 23, and 28 and submit that claims 7, 11, 23, and 28 are in condition for allowance.

SUMMARY

For the reasons explained above, claims 1-6, 8-10, 13, 14, 16-22, and 24-27 were not properly rejected under 35 U.S.C. §102(e) for anticipation by Warkentin et al. (U.S. Patent No. 6,824,512), and the rejection of these claims constitutes clear error. Appellant respectfully submits that that this document does not render the claims anticipated.

For the reasons explained above, claims 7, 11, 23, and 28 were not properly rejected under 35 U.S.C. §103(a) over Warkentin et al. in view of Mann et al. (U.S. Patent Application Publication No. 2004/0147969), and the rejection of these claims constitutes clear error. It is respectfully submitted that these documents do not render the claims obvious.

Therefore, Appellant respectfully requests reversal of the rejections of the pending claims and submit that the pending claims are in condition for allowance. If necessary please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Nellie Nuhring /Nellie Nuhring/
Name Signature

8. CLAIMS APPENDIX

1. A medication storage, therapy and consumption management system, comprising:

an implantable device configured to implantably electrically monitor fluid retention;

an external, non-ambulatory pill-dispensing containment unit configured to accessibly house diuretic medication, the containment unit including a diuretic medication pill receptacle configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication; and

a health management host system coupled to the containment unit in a manner that allows data transmission;

said containment unit including a communications and control system that records and transmits data relating to a medication event, the medication event data including information related to the dispensing, said containment unit control system further providing for transmitting and receiving medication therapy data;

said health management host system configured to receive data related to the medication event, receive patient physiological data including fluid retention data collected by the implantable device, analyze the patient physiological data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data.

2. The system of claim 1, wherein the patient physiological data comprises weight and neuro-hormonal data.

3. The system of claim 1, wherein the containment unit is further configured to communicate wirelessly with said health management host system.

4. The system of claim 1, wherein the containment unit is configured with a display device to display the diuretic medication therapy regimen.

5. The system of claim 4, wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system.

6. The system of claim 1, wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein.

7. The system of claim 1, wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level.

8. The system of claim 1, wherein said health management host system processes said data related to the medication event data and said patient physiological data in response to the diuretic medication therapy regimen, and in response thereto provides for the generation of an updated diuretic medication therapy regimen.

9. An electronic patient health management system, comprising:

an implantable medical measurement device for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data;

an external, non-ambulatory, pill-dispensing medication therapy management device configured to accessibly house diuretic medication, the medication therapy management device including a diuretic medication pill receptacle configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication, the medication therapy management device being configured to store medication event data related to at least one of dispensing or patient consumption of medication, the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement device and the medication event data; and

a patient wellness host system, communicatively coupled to the medication therapy management device, configured to receive the processed data and use the processed data to generate a diuretic medication therapy regimen.

10. The system of claim 9, wherein the medication therapy management device is further configured to provide a reminder to a patient when it is time to take the medication.

11. The system of claim 9, comprising an external medical measurement device for measuring data related to at least one patient physiological health factor.

13. The system of claim 9, wherein the medical measurement device is communicatively coupled to the patient wellness host system via an Internet connection.

14. The system of claim 9, wherein the medical measurement device is communicatively coupled to the patient wellness host system via a wireless communication link.

16 The system of claim 9, wherein data related to the at least one patient physiological health factor comprises data monitored by an implantable device.

17. The system of claim 9, wherein data related to the at least one patient physiological health factor comprises weight data.

18. The system of claim 9, wherein data related to the at least one patient physiological health factor comprises neuro-hormonal data.

19. The system of claim 9, wherein data related to the at least one patient physiological health factor comprises renal function data.

20. The system of claim 9, wherein the patient wellness host system is configured to process said data received in order to develop a therapeutic response.

21. The system of claim 20, wherein the developed therapeutic response comprises revising medication regime, maintaining current medication regime, and recommending a diet plan.

22. The system of claim 9, wherein the patient wellness host system is a computer, which comprises with a memory, a processor and a user interface.

23. The system of claim 9, wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level.

24. A method for remote management of a medication therapy using an external, non-ambulatory, pill-dispensing medication containment unit, the method comprising:

alerting a patient when it is time to carry out a diuretic medication step of a first therapeutic plan;

sensing when the external, non-ambulatory, pill-dispensing medication containment unit is engaged and recording the same as a medication event, the containment unit including a diuretic medication pill receptacle configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication, wherein the medication event data includes information related to the dispensing;

implantably electrically sensing fluid retention data;

receiving patient physiological data including the implantably-sensed fluid retention data;

processing said patient physiological data and said medication event data; and

generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data.

25. The method of claim 24, wherein the alerting step comprises notifying the patient to consume at least one of medication and food.

26. The method of claim 24, wherein the alerting step comprises causing the external, non-ambulatory medication containment unit to generate one of the following, an audible sound, to vibrate and to communicate with a second external device which responsively prompts the patient to act.

27. The method of claim 24, wherein the receiving step is initiated by an external device transmitting patient physiological data to the external, non-ambulatory medication containment unit.

28. The method of claim 24, wherein the receiving step is initiated when the external, non-ambulatory medication containment unit interrogates an external device.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDINGS APPENDIX

None.